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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,679	02/17/2005	Hae-Young Suh	DE1617	3749

1109 7590 04/09/2008

ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
04/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,679	SUH ET AL.	
	Examiner	Art Unit	
	DAVID MONTANARI	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-8 in the reply filed on 3/6/2008 is acknowledged.

Claims 9-14 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/6/2008.

1. Claims 1-8 are examined in the instant application.

Claim Objections

Claims 5-8 are objected to for depending from rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez-Ramos et al. (2000, Exp. Neurology, Vol. 164, pgs. 247-256), Inoue et al. (2001, Genes to Cells, Vol. 6, pgs. 977-986) and Elwood et al. (1998, Blood, Vol. 91, pgs. 3756-3765).

The specification teaches on pg. 1 line 13 that "Mesenchymal stem cells (MSC) are multipotent bone marrow stromal cells aiding hematopoiesis". For the purposes of this rejection,

the bone marrow stromal cells that are differentiated into neuronal cells taught in the art below are applicable over the claimed MSC's of the invention.

Sanchez-Ramos teach that bone marrow stromal cells (BMSC) can be differentiated into neuronal cells when cultured with BDNF or EGF and are confirmed as neuronal cells by their expression of nestin protein and mRNA (pg. 247, Abstract and pg. 249, col. 1). Sanchez-Ramos does not teach a method of transdifferentiating MSC's with a bHLH transcription factor.

Inoue et al. teach that "The bHLH genes Mash1, Math3 and Neurogenin are expressed by neural precursor cells and differentiating neurones. Mis-expression of these bHLH genes in precursor cells promotes the neuronal fate determination while inhibiting the glial fate" (pg. 977, col. 1, parag. 2). Inoue continue to teach that "In contrast, genes that can functionally antagonize such neurogenic bHLH genes have been shown to induce gliogenesis at the expense of the neuronal fate: the bHLH genes Hes1, Hes5 and Hesr2 and the HLH genes Id1 and Id3 are capable of antagonizing neurogenic bHLH genes and inducing gliogenesis" (pg. 977 col. 2 parag. 1). Inoue does not teach a method of transdifferentiating MSC's with a bHLH transcription factor.

Ellwood et al. teaches that the product of the SCL gene is a bHLH transcription factor that is essential for the development of hematopoietic stem cells (pg. 3756, Abstract). Ellwood continues to teach that in order to force expression of SCL in CD34+ cells isolated from human bone marrow, an SCL retrovirus was used to transduce said cells (pg. 3756, Abstract and pg. 3760, col. 2, parag. 2, 2nd to last sentence). Ellwood does not teach a method of transdifferentiating MSC's with a bHLH transcription factor.

Thus the ordinary artisan would have been motivated at the time of filing to transdifferentiate MSC into neuronal cells by transducing a bHLH transcription factor in a viral vector given the teachings and motivations of Sanchez-Ramos that BSMC can be differentiated into neuronal cells by the culturing with either BDNF or EGF. Further motivation is provided by Inoue teaching that certain bHLH transcription factors, including Neurogenin, have the ability to direct precursor cells to a neuronal fate and not a glial cell fate. Additional motivation is provided by Ellwood teaching that a retroviral vector is useful for the for expression of a gene encoding a bHLH transcriptions factor via transduction. Thus the cited art provides the requisite teachings and motivation to make and use the claimed method.

Claims 5-8 are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.
AU 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632